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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/528,082

03/14/2005

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08/29/2008

EXAMINER

BLANCHARD, DAVID J

ART UNIT

PAPER NUMBER

1643

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/528,082	<b>Applicant(s)</b> MOSCA, JOSEPH D	
	<b>Examiner</b> David J. Blanchard	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 16-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 16-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Claims 9-15 are cancelled.  
Claims 1-5 and 8 have been amended.  
Claims 16-26 have been added.
2. Claims 1-8 and 16-26 are under consideration.
3. This Office Action contains New Grounds of Rejections

### ***Objections/Rejections Withdrawn***

4. The objection to the specification as lacking a priority claim to prior application PCT/US04/29671 is withdrawn in view of the amendments to the specification filed 5/19/2008.
5. the rejection of claims 3-5 under 35 U.S.C. 112, second paragraph, as being indefinite for reciting "derived" and "tumor-derived" is withdrawn in view of the amendments to the claims.

### ***Rejections Maintained and New Grounds of Rejections***

#### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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7. The rejection of claims 1-7 and now applied to newly added claims 16-20 and 23-26 under 35 U.S.C. 102(e) as being anticipated by Hiserodt et al (U.S. 6,277,368 B1, filed 7/24/1997).

The response filed 5/19/2008 states that Hiserodt et al fail to teach the virus or virus-like particles as presently claimed and these particles are released from cells and “acquire” the immune stimulatory properties of the cells and it is these particles that are able to induce immune responses against a tumor antigen in the context of costimulatory molecule. Applicants' arguments have been fully considered but are not found persuasive. The specification does not define the phrase “biologically generated virus or virus-like particle”. Hiserodt et al teach using a viral vector such as adenoviral and retroviral vectors (inclusive to HIV-1 gag vectors), wherein the viral vector is first replicated, and then an entire population of cells may be infected and altered. Thus, the genetically modified tumor cells or infected tumor cells with an adenoviral and retroviral vector as taught by Hiserodt et al are reasonably interpreted to read upon “biologically generated virus or virus-like particle with a cellular membrane from a host cell...” in the absence of the distinguishing characteristics or a definition of the phrase. Applicant is reminded that during patent examination, the pending claims must be “given their broadest reasonable interpretation consistent with the specification.” The Federal Circuit’s en banc decision in *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005). Applicant always has the opportunity to amend the claims during prosecution, and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified. *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969).

For these reasons and those already of record, the rejection is maintained.

### ***New Grounds of Rejections***

#### ***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is indefinite for reciting "tumor-derived". The claim is indefinite for reciting "tumor-derived" as the exact meaning of the term is not known. The term "tumor-derived" is not one which has a universally accepted meaning in the art nor is it one which has been adequately defined in the specification. The primary deficiency in the use of this phrase is the absence of an ascertainable meaning for said term. Since it is unclear how the tumor cells are to be derivatized to yield the class of derivatives referred to in the claims, there is no way for a person of skill in the art to ascribe a discrete and identifiable class of compounds to said term. In addition, the term "tumor-derived" does not appear to be clearly defined in the specification, and the term can refer to tumor cells modified genetically by amino acid substitutions, insertions, or deletions, modified by antisense, modified by cell fusion, modified chemically or even tumor cell mimetics. In absence of a single defined art recognized meaning for the phrase and lacking a definition of the term in the specification, one of skill in the art could not determine the metes and bounds of the claim.

### ***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. The rejection of claims 21-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Nawrocki et al (Cancer treatment Reviews, 25:29-46, 1999).

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Nawrocki et al teach a method of treating cancer in a subject comprising inducing a cellular immune response involving T cells (i.e., “effector cell immune response”) against cancer cells comprising administering autologous or allogenic tumor cells or autologous non-tumor cells (e.g., dendritic cells, fibroblasts, monocytes) modified using a retroviral, non-viral lipid, or adenoviral gene delivery system to express a tumor antigen, a B7 co-stimulatory molecule and a cytokine (see entire document, particularly abstract, pp. 38-41). Thus, the genetically modified tumor cells or infected tumor cells with an adenoviral and retroviral vector as taught by Nawrocki et al are reasonably interpreted to read upon “biologically generated virus or virus-like particle with a cellular membrane from a host cell...” in the absence of the distinguishing characteristics or a definition of the phrase.

Thus, Nawrocki et al anticipates the claims.

12. No claim is allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832.

The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Blanchard/  
Primary Examiner, A.U. 1643